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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,046	07/21/2005	Lisa Marie Shewchuk	PU4804USW	7149
23347 7590 03/13/2008 GLAXOSMITHKLINE CORPORATE INTELLECTUAL PROPERTY, MAI B475 FIVE MOORE DR., PO BOX 13398 RESEARCH TRIANGLE PARK, NC 27709-3398				
EXAMINER STEADMAN, DAVID J				
ART UNIT		PAPER NUMBER		
1656				
NOTIFICATION DATE		DELIVERY MODE		
03/13/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/543,046

**Applicant(s)**

SHEWCHUK ET AL.

**Examiner**

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4, 6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 4, 6 and 10-14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

- [1] Claims 4, 6, and 10-14 are pending in the application.
- [2] Applicant's preliminary amendment to the claims, filed on 6/6/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims. Claims 1-3, 5, and 7-9 are canceled, claims 4 and 6 are amended, and claims 10-14 are added.
- [3] Receipt of an information disclosure statement, filed on 6/6/07, is acknowledged.
- [4] Receipt of a statement of the sameness of the computer readable form and paper copy of the sequence listing filed on 7/21/05 and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, filed on 6/6/07, is acknowledged.

### ***Lack of Unity***

- [5] Applicant's election without traverse of Group II, original claims 4-6, in the reply filed on 6/6/07 is acknowledged.
- [6] Upon reconsideration of the lack of unity in the Office communication filed on 5/7/07 and in view of newly added claims 10-14, the following is a supplemental lack of unity.
- [7] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of the generic invention. These species are

deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows (presented in order of appearance in claim 6):

- i. Interaction with amino acid residue 796
- ii. Interaction with amino acid 797
- iii. Interaction with amino acid 798
- iv. Interaction with amino acid 799
- v. Interaction with amino acid 800
- vi. Interaction with amino acid 724
- vii. Interaction with amino acid 749
- viii. Interaction with amino acid 850
- ix. Interaction with amino acid 848
- x. Interaction with amino acid 860
- xi. Interaction with amino acid 803
- xii. Interaction with amino acid 847
- xiii. Interaction with amino acid 732
- xiv. Interaction with amino acid 725
- xv. Interaction with amino acid 732
- xvi. Interaction with amino acid 749
- xvii. Interaction with amino acid 751
- xviii. Interaction with amino acid 796
- xix. Interaction with amino acid 861

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- xx. Interaction with amino acid 860
- xxi. Interaction with amino acid 772
- xxii. Interaction with amino acid 781
- xxiii. Interaction with amino acid 783
- xxiv. Interaction with amino acid 794
- xxv. Interaction with amino acid 796
- xxvi. Interaction with amino acid 862
- xxvii. Interaction with amino acid 801
- xxviii. Interaction with amino acid 802
- xxix. Interaction with amino acid 803
- xxx. Interaction with amino acid 806
- xxxi. Interaction with amino acid 810

**[8]** The technical feature linking species i to xxxi is a method of ErbB4 inhibitor design. The inventions listed as species i to xxxi do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the species i to xxxi are all amino acids of an ErbB4 having the structural coordinates of Table 2, the amino acids are not regarded as being of similar nature because each of the alternatives is an interaction with an amino acid residue of Table 2 having a distinct three-dimensional structure.

According to PCT Rule 13.2 unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The species of i to xxxi do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of species i to

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xxxi is a method of ErbB4 inhibitor design, which is shown by Rusnack et al. (*Molecular Cancer Therapeutics* 1:85-94, 2001) to lack novelty or inventive step because the reference of Rusnack et al. teaches a method of ErbB4 inhibitor design (see particularly p. 88, Table 1) and does not make it a contribution over the prior art.

**[9]** Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

**[10]** Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

**[11]** Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

**[12]** The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the

election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

**[13]** Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

**[14]** Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

**[15]** The claims will be examined only to the extent they read on the elected subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/  
David J. Steadman, Ph.D.  
Primary Examiner  
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